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**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  
**GOLDENBERG**

Serial No.: 09/965,796

Filed: October 1, 2001

Title: IMMUNOTHERAPY OF B-CELL  
MALIGNANCIES USING ANTI-CD22  
ANTIBODIES

Group Art Unit: 1643

Examiner: Alana M. Harris

Attorney Docket No.: IMMU:007US3

**EFS-WEB****DECLARATION UNDER 37 CFR § 1.132**

**MAIL STOP AMENDMENT**  
COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450

Sir:

I, Kenneth Foon, being duly warned, declare as follows:

1. I am the Director of Clinical Investigation and Program Director for the Leukemia and Lymphoma Program at the University of Pittsburgh Cancer Institute. I have an extensive background in the field of immunotherapy for cancer treatment, as evidenced by my Curriculum Vitae, which is attached. In particular, I have been the principal investigator on clinical trials relating to immunotherapy of various B-cell malignancies. For example, I am currently the principal investigator for a Phase II clinical trial to study effects of a combination of rituximab, fludarabine and cyclophosphamide on patients with previously untreated chronic lymphocytic leukemia.

2. I am familiar with the article Maloney *et al.*, *Blood*, 84(8): 2457-2466 (1994). This article relates to results from a Phase I clinical trial to evaluate the safety of anti-CD20 antibody as a single agent therapeutic.

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3. Maloney 1994 states, on page 2465, that "extension of these studies to patients with minimal disease, using antibody alone or in combination with conventional therapies, may provide the greatest benefit. The disclosure in Maloney that anti-CD20 may be combined with a "conventional therapy" would not have suggested to me therapy with a combination of an anti-CD20 antibody and another antibody, such as an anti-CD22 antibody. This is because "conventional therapies" at the time of the Maloney article, circa 1994, were chemotherapies, not antibody therapies. The current clinical trial which I referenced above in paragraph 1 is just such a combination of the anti-CD20 antibody rituximab with a conventional drug therapy (fludarabine and cyclophosphamide) that is envisioned by Maloney 1994.

4. "Conventional" means "conforming to established practice or accepted standards; traditional" (The American Heritage® Dictionary of the English Language: Fourth Edition - 2000). An investigational drug in Phase I clinical trials cannot be considered a conventional therapy, i.e., it does not conform to established practice or accepted standards." By definition, investigational drugs have not been "accepted." Companies can provide investigational drugs to doctors if they are part of a drug trial covered by an FDA-approved protocol, and such drugs are by definition not conventional, since they are not available for use by any doctor on any patient.

5. In 1994 (and later) antibody therapies were not "conventional," and therefore Maloney's comment regarding the addition of "conventional therapies" to his anti-CD20 antibody suggests to a skilled clinician a combination of the anti-CD20 single antibody therapy with a chemotherapy. It would not have suggested therapy with a combination of antibodies. "Conventional therapies," circa 1994 and later, were chemotherapies. The first approved antibody for therapy of any malignancy was the anti-CD20 antibody rituximab that is the subject of Maloney, but it was not approved until 1997, and therefore there was no cancer therapy with any antibody that was a conventional therapy in 1994.

6. Treatment with anti-CD22 antibody was not conventional circa 1994. For example, Goldenberg *et al.*, *J. Clin. Oncol.*, 9: 548-564 (1991) relates to results from a pilot Phase I study involving a small number of patients to see the feasibility of giving this radiolabeled antibody, involving targeting tumor and organs, doses delivered to tumor and normal organs, and any evidence of efficacy in a small number of patients, and does not establish that treatment with anti-CD22 antibody was "conventional." Juweid *et al.* *Cancer Res.*, 55:5899s-5907s (1995) is a follow-on report of further treatment of patients with low doses and

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initial results of high dose therapy in a Phase I trial. Here again, these were early investigational studies and do not represent conventional therapy.

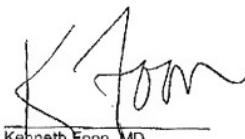
7. Current reviews and texts support the fact that antibody therapy using a combination of antibodies to different targets is not conventional. No such combination therapy has been approved, and even combinations of rituximab with conventional chemotherapy for lymphoma have only been approved by the FDA within the past two years. Although some articles began to discuss the possibility of combination antibody therapies following publication by Immunomedics of their studies of epratuzumab and rituximab in about 2002/2003, none of these indicate that such therapy is "conventional." For example, "What is New in Lymphoma," published in 2004, cites rituximab as an advancement in the treatment of NHL. Efforts to improve the activity of rituximab are noted, and include increasing the number of weekly infusions, delivering higher doses and increasing dose density. Combinations with CHOP are also mentioned. The article references both a Phase II study of a combination of rituximab with epratuzumab and a phase I/II study of the combination of galiximab and rituximab, both of which were reported in 2003, demonstrating that combination antibody therapy was still very much investigational at this later date. Cheson, CA Cancer J Clin, Sep-Oct; 54(5):260-72 (2004).

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I hereby declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date

2/16/07

  
K. Foon

Kenneth Foon, MD

## CURRICULUM VITAE

### BIOGRAPHICAL

**Name:** Kenneth A. Foon, MD      **Birth Date:** 3/7/47  
**Home Address:** 416 William Street      **Birth Place:** Detroit, MI  
Pittsburgh, PA 15211  
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**Business Phone:** (412) 623-5898      **Spouse:** Rebecca A. Garrett, MD  
**Business Fax:** (412) 648-6579

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### EDUCATION AND TRAINING

#### UNDERGRADUATE:

Dates Attended	Name & Location of Institution	Degree Received and Year	Major Subject
1964-1966	University of Michigan		
1966-1968	Wayne State University	BS, 1968	Biology

#### GRADUATE:

Dates Attended	Name & Location of Institution	Degree Received and Year	Major Subject
1968-1972	Wayne State University	M.D, 1972	Medicine

**POSTGRADUATE:**

<b>Dates Attended</b>	<b>Name &amp; Location of Institution</b>	<b>Name of Program Director and Discipline</b>
1972-1973	University of California, San Diego School of Medicine, San Diego, CA	Nathan Zvailler, MD Straight Internal Medicine Internship
1976-1977	Washington VA & Georgetown Hospitals, District of Columbia	Hyman Zimmerman, MD Straight Internal Medicine First Year Residency
1977-1980	University of California, Los Angeles Los Angeles, CA	Martin Cline, MD Fellow in Hematology and Oncology

**ACADEMIC:**

<b>Years Inclusive</b>	<b>Name &amp; Location of Institution</b>	<b>Rank/Title</b>
1980-1981	University of California Los Angeles School of Medicine Los Angeles, CA	Assistant Professor of Medicine (tenure track)
1985-1987	University of Michigan School of Medicine Ann Arbor, MI	Associate Professor of Medicine (with tenure)
1985-1987	University of Michigan School of Medicine Ann Arbor, MI	Associate Chief, Div. of Hematology- Oncology Director of Clinical Hematology
1987-1991	State University of New York at Buffalo Buffalo, NY	Professor, Dept. of Medicine (with tenure)
1987-1991	Roswell Park Cancer Institute Buffalo, NY	Chief, Division of Clinical Immunology
1991-1992	Department of Molecular and Experimental Medicine, The Scripps Research Institute San Diego, CA	Adjunct Member

1991-1992	Ida M. and Cecil H. Green Cancer Center Scripps Clinic and Research Foundation San Diego, CA	Associate Director for Clinical Research
1993-1999	University of Kentucky School of Medicine Lexington, KY	Chief, Div. of Hematology-Oncology Professor of Medicine (with tenure)
1993-1999	Markey Cancer Center University of Kentucky School of Medicine Lexington, KY	Director
1999-2001	University of Cincinnati School of Medicine Cincinnati, OH	Associate Director Division of Hematology-Oncology Professor of Medicine (with tenure)
1999-2001	Barrett Cancer Center University of Cincinnati School of Medicine Cincinnati, OH	Director
2001-2003	Stanford University School of Medicine Stanford, CA	Clinical Professor of Medicine
2003-2006	University of Pittsburgh Cancer Institute	Co-Leader of the Biological Therapeutics Program
2005-Present	University of Pittsburgh Cancer Institute	Interim Director of Minority Outreach
2003-Present	University of Pittsburgh Cancer Institute	Director of Clinical Investigations Co-Leader of the Hematologic Malignancies Program
2003-Present	University of Pittsburgh School of Medicine	Professor of Medicine

## **NON-ACADEMIC**

<b>Years Inclusive</b>	<b>Name &amp; Location of Institution</b>	<b>Rank/Title</b>
1973-1975	National Eye Institute, National Institutes of Health Bethesda, MD and guest worker National Institute of Dental Research, Laboratory of Microbiology and Immunology Bethesda, MD	Research Associate and Lieutenant, U.S. Public Health Service
1975-1976	National Institute of Dental Research, Laboratory of Microbiology and Immunology, National Institute of Health, Bethesda, MD	Clinical Associate and Lieutenant Commander, U.S. Public Health Service
1981-1982	Head, Monoclonal Antibody- Hybridoma Section, Biological Response Modifiers Program, Division of Cancer Treatment, National Cancer Institute Frederick, MD	Senior Investigator and Lieutenant Commander, U.S. Public Health Service
1982-1985	Head, Clinical Investigations Section, Biologic Response Modifiers Program, Division of Cancer Treatment National Cancer Institute Frederick, MD	Senior Investigator and Lieutenant Commander, U.S. Public Health Service (tenured in 1984)
2001-2003	Abgenix Inc. Fremont, CA	Director, Clinical Development for Oncology

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## **CERTIFICATION AND LICENSURE**

### **Specialty Certification:**

<b>Certifying Board</b>	<b>Year</b>
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National Board of Medical Examiners	1973
American Board of Internal Medicine	1978
American Board of Internal Medicine Subspecialty of Hematology	1980
American Board of Internal Medicine Subspecialty of Medical Oncology	1981

**Medical Licensure:**

Licensing Board/State	Year
California (active)	1973
Maryland (inactive)	1973
Michigan (inactive)	1982
New York (inactive)	1987
Kentucky (inactive)	1993
Ohio (inactive)	1999
Pennsylvania (Active)	2003

**MEMBERSHIPS IN PROFESSIONAL AND SCIENTIFIC SOCIETIES**

Organization	Year
American College of Physicians (Fellow)	1978-present
American Society of Hematology	1980-present
American Association for the Advancement of Sciences	1980-present
American Society of Clinical Oncology	1981-present
American Association for Cancer Research	1982-present
The Society of Biological Therapy	1982-present

Clinical Immunology Society	1987-present
Member, Leukemia Committee, Southwest Oncology Group	1987-2001
International Society for Experimental Hematology	1991
Member, Colorectal Disease Committee, National Surgical Adjuvant Breast and Bowel Project	1997-2001
Member, Melanoma Committee, Southwest Oncology Group	1997-2000
Member, Colorectal Committee, American College of Surgeons	1999-2001
Member, Lymphoma, Committee, Eastern Cooperative Oncology Group	2003-Present
Member, Leukemia Committee, ECOG	2003-Present

## HONORS

Title of Award	Year
Alpha Omega Alpha	1971
Dr. A. Ashley Rousuck Award in Internal Medicine (Wayne State University School of Medicine)	1971
Gordon B. Myers Award in Internal Medicine (Wayne State University School of Medicine)	1972
Medical Degree Awarded with High Distinction, Wayne State University	1972
Fellow of the American College of Physicians	1982
Distinguished Alumni Award, Wayne State University School of Medicine	1987

Michigan Science Trailblazer	1988
Faculty Research Award for Excellence in Research, University of Kentucky	1998
Chairman's Award for Excellence in Research, University of Kentucky, Dept. of Internal Medicine	1998

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## PUBLICATIONS

### 1. Refereed Articles

1. **Foon KA**, Wahl SM, Oppenheim JJ and Rosenstreich DL: Serotonin-induced production of a monocyte chemotactic factor by human peripheral blood leukocytes. *J Immunol* 117:154-1552, 1976.
2. Sher NA, **Foon KA**, Fishman ML and Brown T: Demonstration of monocyte chemotactic factors in the aqueous humor during experimental immunogenic uveitis in the rabbit. *Infect Immun* 13:1110-1116, 1976.
3. Sher ND, Douglas DJ, Mindrup E, Minaii LA and **Foon KA**: Macrophage migration inhibition factor activity in the aqueous humor during experimental corneal xenograft and allograft rejection. *Am J Ophthalmol* 82:858-865, 1976.
4. **Foon KA**, Yuen K, Ballantine E and Rosenstreich D: Analysis of the systemic corticosteroid sensitivity of patients with primary open angle glaucoma. *Am J Ophthalmol* 83:167-173, 1977.
5. **Foon KA**, Naiem F, Yale C and Gale RP: Acute myelogenous leukemia: Morphologic subclass and response to therapy. *Leuk Res* 3:171-173, 1979.
6. **Foon KA**, Billing RJ and Terasaki PI: Dual B and T markers in acute and chronic lymphocytic leukemia. *Blood* 55:16-20, 1980.
7. Billing RJ, Clark BM, Koeffler P, **Foon KA** and Terasaki PI: Acute myelocytic leukemia heteroantisera. *Clin Immunol Immunopathol* 16:202-210, 1980.

8. **Foon KA**, Yale C, Clodfelter K and Gale RP: Effect of posttreatment hepatitis on survival of patients with acute myelogenous leukemia. *JAMA*, 244:1806-1807, 1980.
9. **Foon KA**, Fitchen JH, Billing RJ, Belzer MB, Terasaki PI and Cline MJ: An antithymocyte serum non-cytotoxic to myeloid progenitor cells: Candidate serum for prevention of graft-versus-host disease in bone marrow transplantation. *Clin Immunol Immunopathol* 16:416-422, 1980.
10. **Foon KA**, Billing RJ, Terasaki PI and Cline MJ: Immunologic classification of acute lymphocytic leukemia: Implications for normal lymphoid differentiation. *Blood* 56:1120-1126, 1980.
11. **Foon KA**, Herzog P, Billing R, Terasaki PI and Feig S: Immunologic classification of childhood acute lymphocytic leukemia. *Cancer* 47:280-284, 1981.
12. **Foon KA**, Naeim F, Saxon A, Stevens R and Gale RP: Leukemia of T-helper lymphocytes: Clinical and functional characterization. *Leuk Res* 5:1-10, 1981.
13. **Foon KA**, Billing RJ, Fitchen JH, Belzer MB, Drew SI and Terasaki PI: An antigen expressed by cells of the myelo-monocytic lineage. *Am J Hematol* 10:259-267, 1981.
14. Belzer M, Fitchen JH, Ferrone S, **Foon KA**, Billing RJ and Golde DW: Expression of HLA-DR antigen on human erythroid progenitor cells as determined by monoclonal anti-DR antibodies and heteroantisera. *Clin Immunol Immunopathol* 20:111-115, 1981.
15. Gale RP, **Foon KA**, Cline MJ and Zighelboim J: Intensive chemotherapy for acute myelogenous leukemia. *Ann Intern Med* 94:753-757, 1981.
16. Fitchen JH, **Foon KA** and Cline MJ: The antigenic characteristics of hematopoietic stem cells. *N Engl J Med* 305:17-25, 1981.
17. **Foon KA**, Zighelboim J, Yale C and Gale RP: Intensive chemotherapy is the treatment of choice for elderly patients with acute myelogenous leukemia. *Blood* 58:467-470, 1981.
18. **Foon KA**, Filderman A and Gale RP: Histiocytic lymphoma following resolution of sarcoidosis. *Med Pediatr Oncol* 9:325-331, 1981.
19. Hoffman F, **Foon KA**, Smith D, Kransler J, Ciccarelli J and Billing R: Functional properties of subsets of T lymphocytes defined by special antigens. *Clin Exp Immunol* 44:476-484, 1981.
20. Hocking WG, Billing R.J, **Foon KA** and Golde DW: Human alveolar macrophages express DR antigens. *Blood* 58:1040-1042, 1981.
21. Linker-Israeli M, Billing RJ, **Foon KA** and Terasaki PI: Monoclonal antibodies reactive with acute myelogenous leukemia cells. *J Immunol* 127:2473-2477, 1981.

22. Billing R, Terasaki PI, Sugich L and **Foon KA**: Detection of differentiation antigens by use of monoclonal antibodies. *J Immunol Methods* 47:289-294, 1981.
23. Schroff RW, **Foon KA**, Billing RJ and Fahey JL: Immunologic classification of lymphocytic leukemias based on monoclonal antibody-defined cell surface antigens. *Blood* 59:207-215, 1982.
24. **Foon KA** and Haskell CM: Inadvertent overdose with lomustine (CCNU) followed by hematologic recovery. *Cancer Treat Reports* 66:1241-1241, 1982.
25. **Foon KA** and Gale RP: Controversies in the therapy of acute myelogenous leukemia. *Am J Med* 72:963-979, 1982.
26. **Foon KA**, Schroff RW and Gale RP: Cell surface markers on leukemia and lymphoma cells: Recent advances. *Blood* 60:1-19, 1982.
27. Billing RJ, **Foon KA** and Linker-Israeli M: The immunological classification of leukemia based on a rapid microcytotoxicity test. *Clin Exp Immunol* 49:142-148, 1982.
28. Schroff RW and **Foon KA**: Heterogeneity in a lymphoid tumor: Co-expression of T and B surface markers. *Blood* 60:373-380, 1982.
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30. **Foon KA**, Bernhard MI and Oldham RK: Monoclonal antibody therapy: Assessment by animal tumor models. *J Biol Response Mod* 1:277-304, 1982.
31. Sherwin SA, Knost JA, Fein S, Abrams PG, **Foon KA**, Ochs JJ, Schoenberger C, Maluish AE and Oldham RK: A multiple dose phase I trial of recombinant leukocyte A interferon in cancer patients. *JAMA* 248:2461-2466, 1982.
32. Key ME, Bernhard MI, Hoyer LC, **Foon KA**, Oldham RK and Hanna MG: Guinea pig line 10 hepatocarcinoma model for monoclonal antibody serotherapy: *In vivo* localization of a monoclonal antibody in normal and malignant tissues. *J Immunol* 120:1451-1457, 1983.
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34. Bernhard MI, **Foon KA**, Oeltmann TN, Key ME, Hwang KM, Clarke CG, Christensen WL, Hoyer LC, Hanna MG and Oldham RK: Guinea pig line 10 hepatocarcinoma model:

Characterization of monoclonal antibody and *in vivo* effect of unconjugated antibody and antibody conjugated to diphtheria toxin A chain. *Cancer Res* 43:4420-4428, 1983.

35. Bernhard MI, Hwang KM, **Foon KA**, Keenan A, Kessler R, Frincke, Tallum DJ, Hanna MG, Peters L and Oldham RK: Localization of <sup>111</sup>In- and <sup>125</sup>Io-labeled monoclonal antibody in guinea pigs bearing line 10 hepatocarcinoma tumors. *Cancer Res* 43:4429-4433, 1983.
36. **Foon KA**, Smalley RV, Riggs CW and Gale RP: The role of immunotherapy in acute myelogenous leukemia. *Arch Intern Med* 143:1726-1734, 1983.
37. Knost JA, Sherwin SA, Abrams PG, Ochs JJ, **Foon KA**, Williams R, Tuttle R and Oldham RK: The treatment of cancer patients with human lymphoblastoid interferon: A comparison of two routes of administration. *Cancer Immunol Immunother* 15:148-155, 1983.
38. Abrams PG, Knost JA, Clarke G, Wilburn S, Oldham RK and **Foon KA**: Determination of the optimal human cell lines for development of human hybridomas. *J Immunol* 131:1201-1204, 1983.
39. **Foon KA**, Buescher S, Kimball ES, Huang LC, Stevenson HC, Clarke G, Gregoria T and Harley JB: Monoclonal antibody to human eosinophils recognizing 95 kD surface membrane antigen. *Hybridoma* 2:393-402, 1983.
40. Stevenson HC, **Foon KA**, Kanapa DJ, Favilla T, Beman J and Oldham RK: The potential value of cytapheresis for adoptive immunotherapy of cancer patients. *Plasma Ther Transfus Technol* 5:237-250, 1984.
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43. Oldham RK, Morgan AC, Woodhouse CS, Schroff RW, Abrams PG and **Foon KA**: Monoclonal antibodies in the treatment of cancer: Preliminary observations and future prospects. *Med Oncol Tumor Pharmacother* 1:51-62, 1984.
44. Abrams PG, Ochs JJ, Giardina SL, Morgan AC, Wilburn SB, Wilt AR, Oldham RK and **Foon KA**: Production of large quantities of human immunoglobulin in the ascites of athymic mice: Implication for the development of anti-human idiotype monoclonal antibodies. *J Immunol* 132:1611-1613, 1984.

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47. Champlin R, Jacobs A, Gale RP, Boccia R, Elashoff R, **Foon KA** and Zighelboim J: Prolonged survival in acute myelogenous leukemia without maintenance chemotherapy. Lancet 1:894-896, 1984.
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49. **Foon KA**, Neubauer RH, Wikstrand CJ, Schroff RW, Rabin H and Seeger RC: Human Thy-1 antigen: Distribution on human and non-human primate hematopoietic cells. J Immunogenet 11:233-244, 1984.
50. **Foon KA**, Schroff RW, Bunn RA, Mayer D, Abrams PG, Fer MF, Ochs JJ, Bottino GC, Sherwin SA, Herberman RB and Oldham RK: Effects of monoclonal antibody therapy in patients with chronic lymphocytic leukemia. Blood 64:1085-1094, 1984.
51. Oldham RK, **Foon KA**, Morgan AC, Woodhouse C, Schroff RW, Abrams PG, Fer MF, Schoenberger C, Farrell M, Kimball E and Sherwin SA: Monoclonal antibody therapy of malignant melanoma: *In vivo* localization in cutaneous metastasis after intravenous administration. J Clin Oncol 2:1235-1244, 1984.
52. Reynolds CW and **Foon KA**: T-lymphoproliferative disease and related disorders in man and experimental animals. A review of the clinical, cellular and functional characteristics. Blood 64:1146-1158, 1984.
53. Fer MF, Bottino GC, Sherwin SA, Hainesworth JD, Abrams PG, **Foon KA** and Oldham, RK: Atypical tumor lysis syndrome in a patient with T-cell lymphoma following recombinant interferon therapy. Am J Med 77:953-956, 1984.
54. Bunn PA, **Foon KA**, Idhe DC, Winkler CF, Zeffren J, Sherwin SA and Oldham RK: Recombinant leukocyte A interferon: An active agent in advanced cutaneous T-cell lymphoma. Ann Intern Med 101:484-487, 1984.
55. Stevenson HC, Kimball ES, Buescher S, Clarke G and **Foon KA**: Monoclonal antibody to human monocytes and granulocytes: Isolation of membrane antigens and lack of effect on leukocyte functions *in vitro*. Hybridoma 3:247-261, 1984.

56. **Foon KA**, Sherwin SA, Abrams PG, Longo DL, Fer MF, Stevenson HC, Ochs JJ, Bottino GC, Schoenberger CS, Zeffren J, Jaffe ES and Oldham RK: Treatment of advanced non-Hodgkin's lymphoma with recombinant leukocyte A interferon. *N Engl J Med* 311:1148-1152, 1984.
57. Morgan AC, Woodhouse CS, Knost JA, Abrams PG, Clarke GC, Arthur LO, McIntrye R, Ochs JJ, **Foon KA**, Hanna MG and Oldham RK: Monoclonal antibodies to human colorectal tumor-associated antigens: Improved elicitation and subclass restriction. *Hybridoma* 3:233-245, 1984.
58. Sherwin SA, **Foon KA**, Oldham RK, Abrams PG, Heyman MR, Ochs JJ, Watson R and Maluish A: A preliminary phase I trial of partially purified interferon-gamma (IFN-gamma) in patients with disseminated cancer. *Biol Response Mod* 3:599-607, 1984.
59. Bunn PA, Carrasquillo JA, Keenan AM, Schroff RW, **Foon KA**, Hsu SM, Gazdar AF, Reynolds JJ, Perentesis P and Larson SM: Imaging of T-cell lymphoma by radiolabeled monoclonal antibody. *Lancet* 1219-1221, 1984.
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61. Schroff RW, **Foon KA**, Wilburn SB, Oldham RK and Morgan AC: Human anti-murine immunoglobulin responses in patients receiving monoclonal antibody therapy. *Cancer Res* 45:879-885, 1985.
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65. Giardina SL, Schroff RW, Woodhouse CS, Golde DW, Oldham RK, Cleary ML, Sklar J, Pritikin N and **Foon KA**: Detection of two malignant B-cell clones in a single patient using anti-idiotype monoclonal antibodies and immunoglobulin gene rearrangement. *Blood* 66:1017-1021, 1985.
66. Giardina SL, Schroff RW, Kipps TJ, Woodhouse CS, Abrams PG, Rager HC, Morgan AC and **Foon KA**: The generation of monoclonal anti-idiotype antibodies to human B-cell derived leukemias and lymphomas. *J Immunol* 135:653-658, 1985.

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72. Bunn PA Jr, Ihde DC and **Foon KA**: The role of recombinant leukocyte A interferon in the therapy of cutaneous T-cell lymphomas. *Cancer* 57:1315-1321, 1986.
73. **Foon KA** and Todd RF III: Immunologic classification of leukemia and lymphoma. *Blood* 68:1-31, 1986.
74. Giardina SL, **Foon KA**, Beatty SM and Morgan AC Jr: Evaluation of alternative methodologies for the generation of monoclonal anti-idiotypic antibodies to human B-cell derived leukemias and lymphomas. *J Immunol Methods* 89:1-7, 1986.
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## **2. Reviews, invited published papers, proceedings of conference and symposia, monographs, books and book chapters.**

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### 3. Published Abstracts

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155. M.A. Melan, **K.A. Foon**, S.M. Marks, and J.A. Kant. Immunoglobulin Heavy Chain (IgH) Gene Somatic Hypermutation Status Using Homoduplex-Separated RT-PCR Products. American Society of Hematology 46<sup>th</sup> Annual Meeting program and Abstracts, Blood 104:11; Pt 2 of 2 Pts, 2004.
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157. N.A. DeMonaco, M. Wu, J. Osborn, T. Evans, **K.A. Foon**, S.H. Swerdlow, J.A. Kant, J. Joyce, S. Land, and S.A. Jacobs. Phase II trial of abbreviated CHOP-Rituximab followed by <sup>90</sup>Y Ibritumomab Tiuxetan (Zevalin) and Rituximab in Patients with Previously-Untreated Follicular Non-Hodgkin Lymphoma (NHL). American Society of Hematology 47<sup>th</sup> Annual Meeting program and Abstracts, Blood 106:11; Pt 1 of 2 Pts, 2005.
158. A.G. Brickner, J.K. Mito, X. Feng, T. Nishida, L. Fairfull, R.E. Ferrell, **K.A. Foon**, S.R. Riddell, and E.H. Warren. An alternative transcript of the PANE1 gene encodes a minor histocompatibility antigen that is selectively expressed in resting CD19+ cells and B-CLL. American Society of Hematology 47<sup>th</sup> Annual Meeting program and Abstracts, Blood 106:11; Pt 1 of 2 Pts, 2005.
159. S.A. Jacobs, S.A. Swerdlow, N. Avril, N. Vidnovic, **K.A. Foon**, A.M. Harrison, and K.S. McCarty. Localization of yttrium 90 ibritumomab tiuxetan (<sup>90</sup>Y IT) in patients with CD20+ non-Hodgkin's Lymphoma (NHL). 2005 ASCO Annual Meeting Proceedings; J Clin Onc, Vol. 23, No. 16S Part I of II, 2005.
160. A. A. Tarhini, S. Land, F. Lim, G. J. Kiefer, L. Pietragallo, R. A. Pinkerton, M. Sulecki, D. Meissner, P. M Schaefer, **K.A. Foon**. Early results of modified fludarabine, cyclophosphamide, and rituximab (mFCR) for patients with previously untreated advanced chronic lymphocytic leukemia (CLL). 2006 ASCO Annual Meeting Proceedings; J Clin Onc, Vol. 24, No. 18S Part I of II, 2006.

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#### 4. Other Publications

1. **Foon KA** and Gale RP: Post-transfusion hepatitis in acute myelogenous leukemia. *JAMA* 246:216, 1981 (letter)
2. **Foon KA**, Zighelboim J and Gale RP: Treatment of acute myelogenous leukemia in older patients. *N Engl J Med* 305:1470, 1981. (letter)
3. **Foon KA**: Treatment of B-cell lymphoma with monoclonal anti-idiotype antibody. *N Engl J Med* 307:686, 1982. (letter)
4. Bernhard MI, **Foon KA**, Oldham RK and Keenan A: The importance of traditional methods of measuring tracer biodistributions. *Cancer Res* 44:2731-2732, 1984. (letter)
5. **Foon KA** and Dougher G: Increased growth of eyelashes in a patient given leukocyte A interferon. *N Engl J Med* 311:1259, 1984. (letter)
6. **Foon KA** and Schroff RW: The uses of monoclonal antibodies in the diagnosis and treatment of leukemia and lymphoma. *In: In Vitro Monograph*, No. 5. 1984, pp 169-188.
7. Abrams PG, McClamrock EA and **Foon KA**: Evening administration of alpha interferon. *N Engl J Med* 312:443-444, 1985. (letter)
8. Reynolds CW, **Foon KA** and Herberman RB: Terminology in T $\gamma$  lymphoproliferative disease. *Blood* 66:248-249, 1985. (letter)
9. **Foon KA**: Interferon-alpha: The next decade. *Interactions* 1:3, 1986. (editorial)
10. **Foon KA**: Interferons. Hoffman La Roche, 1986. (video)
11. **Foon KA**: Biological therapy of chronic myelogenous leukemia. *Oncology* 1:49-52 1987. (editorial)
12. **Foon KA**: Application of monoclonal antibodies in the diagnosis and therapy of cancer. NeoRx Pharm Inc, 1988, pp 1-27. (monograph)
13. **Foon KA**: Antibody Structure and Function. NeoRx Pharm Inc, 1988. (video).

14. **Foon KA:** Therapy of Acute Leukemia: Recent Progress and Future Directions. Wyeth Labortories, 1988. (video)
15. **Foon KA**, Champlin RE and Gale RE: Therapy of acute lymphoblastic leukemia. UCLA Symposium. In: *Acute Lymphoblastic Leukemia*, Vol. 108., pp 157-196, 1990.
16. Vaickus L and **Foon KA:** Clinical immunology at Roswell Park Cancer Institute. Biotherapy of cancer. Oncoline, pp 3-4, 1990. (editorial)
17. Foon KA, Gale RP: Is there a T-cell form of chronic lymphocytic leukemia. Leukemia 6:867-8, 1992. Leukemia 7:916-8, 1993. (letter)
18. **Foon KA:** Cancer Vaccine Therapy: New Approaches, Video Journal of Oncology, Secaucus, NJ 1993. (video)
19. **Foon KA** and Bhattacharya-Chatterjee M. Idiotype vaccines in the clinic. Nature Med 4:870, 1998. (letter)

## TEACHING

Biotherapy: New Opportunities for Cancer Treatment, Grand Rounds, Scripps Clinic and Research Foundation, La Jolla, CA, February 28, 1992.

Acute Leukemia, Internal Medicine Residency Program, University of Kentucky Medical Center, Lexington, KY, August 16, 1993.

Hodgkin's Disease, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, September 10, 1993.

Biologic Therapy and Growth Factors, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, October 8, 1993.

Anti-Idiotype Immunotherapy in Cancer Patients, Lecture-Division of Clinical Chemistry, University of Kentucky Hospital, Lexington, KY, April 27, 1994.

Chronic Lymphocytic Leukemia, Internal Medicine Grand Rounds, University of Kentucky Medical Center, Lexington, KY, July 6, 1994.

Acute Leukemia, Internal Medicine Residency Program, University of Kentucky Medical Center, Lexington, KY, August 16, 1994.

Anti-Idiotype Vaccine Therapy of CEA positive tumors, Internal Medicine Research Seminar, University of Kentucky Medical Center, Lexington, KY, September 8, 1994.

Melanoma, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, February 3, 1995.

Lymphoma, Internal Medicine Residency Program, University of Kentucky Medical Center, Lexington, KY, March 23, 1995.

Chronic Lymphocytic Leukemia, Internal Medicine Residency Program, University of Kentucky Medical Center, Lexington, KY, April 28, 1995.

Overview of the Cancer Center, Health Administration, University of Kentucky Medical Center, June 22, 1995.

Non-Hodgkin's Lymphoma, Internal Medicine Residency Program, University of Kentucky Medical Center, Lexington, KY, September 11, 1995.

Hodgkin's Disease, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, September 15, 1995.

Non-Hodgkin's Lymphoma, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, September 29, 1995.

Chronic Lymphoid Leukemias, Hematology-oncology grand Rounds, Conference, University of Cincinnati, Cincinnati, OH, September 28, 2000

Colon Cancer, Internal Medicine residency Program, University of Cincinnati, Cincinnati, OH, September 27, 2000

Non-Hodgkin's Lymphoma, Internal Medicine residency Program, University of Cincinnati, Cincinnati, OH, June 26, 2000

Melanoma, Internal Medicine Residency Program, University of Cincinnati, Cincinnati, OH, April 14, 2000.

Lymphoma, Internal Medicine Residency Program, University of Cincinnati, Cincinnati, OH, March 13, 2000.

Anti-Idiotype Cancer Vaccines, Children's Hospital Medical Center Research Foundation, Basic Sciences, Cincinnati, OH, January 31, 2000.

Cancer Research, Division of Pharmacology, Ph.D. Program, University of Cincinnati, OH, January 7, 2000.

Lymphomas, Internal Medicine Residency Program, University of Cincinnati, Cincinnati, OH, January 6, 2000.

Melanoma, Internal Medicine Residents, University of Cincinnati Hospital, June 24, 1999.

Anti-Idiotype Cancer Vaccines, Children's Hospital Medical Center Research Foundation, Basic Scientists, January 31, 2000.

Cancer Research, Division of Pharmacology, Ph.D. Program, University of Cincinnati College of Medicine, January, 7, 2000.

Lymphomas, Internal Medicine Residents, University of Cincinnati Hospital, January 6, 2000

Melanoma, Internal Medicine Residents, Univeristy of Cincinnati Hospital, Cincinnati, OH, December 9, 1999.

Lymphomas, Internal Medicine Residents, University of Cincinnati Hospital, October 4, 1999.

Lymphomas, Internal Medicine Residents, University of Cincinnati Hospital, September 14, 1999.

A Novel Immunotherapeutic Approach for the Adjuvant Treatment of Colon Cancer, Internal Medicine Grand Rounds, University of Kentucky Medical Center, Lexington, KY, September 4, 1996.

Melanoma, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, August 16, 1996.

Acute Leukemia, Internal Medicine Residency Program, University of Kentucky Medical Center, Lexington, KY, August 8, 1996.

Low Grade Lymphomas, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, June 28, 1996.

Problem Based Learning Tutor Session, Internal Medicine, University of Kentucky Medical Center, April 1-15, 1996.

Leukemia and Lymphoma, Physician Assistants Lecture, University of Kentucky Medical Center, March 7, 1996.

Acute Leukemias, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, February 2, 1996.

Non-Hodgkin's Lymphoma, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, September 29, 1995.

Hodgkin's Disease, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, September 15, 1995.

Low Grade Lymphomas, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, June 28, 1996.

Problem Based Learning Tutor Session, Internal Medicine, University of Kentucky Medical Center, April 1-15, 1996.

Leukemia and Lymphoma, Physician Assistants Lecture, University of Kentucky Medical Center, March 7, 1996.

Acute Leukemias, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, February 2, 1996.

Grand Rounds, University of Cincinnati Hospital, Cincinnati, OH, 2004.

Medical Grand Rounds, University of Pittsburgh School of Medicine, Department of Medicine, Division of Hematology/Oncology, 2004

Presentations for Lymphoma/Leukemia Tumor Board, University of Pittsburgh School of Medicine, Department of Medicine, Division of Hematology/Oncology, 2003-2006.

Presentations for Hematologic Malignancies Program Seminar Series, University of Pittsburgh School of Medicine, Department of Medicine, Division of Hematology/Oncology, 2003-2006.

Presentations for Biologic Therapeutics Committee, University of Pittsburgh School of Medicine, Department of Medicine, Division of Hematology/Oncology, 2003-2006.

Presentations for Hematologic Malignancy Steering Committee, University of Pittsburgh School of Medicine, Department of Medicine, Division of Hematology/Oncology, 2003-2006.

Nipent<sup>®</sup> (pentostatin) in CLL, Supergen Nipent<sup>®</sup> Strategic Planning Community Advisory Board, Detroit, Michigan, August 6, 2005.

Recent Advances in the Biology and Treatment of Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, Supergen, January 14, 2005

Leukemia and Lymphoma, Houseteaching Staff Lecture Series for Residents, University of Pittsburgh School of Medicine, Department of Medicine, Division of Hematology/Oncology, July 17, 2003; October 24, 2003; and November 7, 2003.

Leukemia and Lymphoma, Houseteaching Staff Lecture Series for Residents, University of Pittsburgh School of Medicine, Department of Medicine, Division of Hematology/Oncology, February 24, 2004; April 1, 2004; May 10, 2004, and June 22, 2004.

Leukemia and Lymphoma, Houseteaching Staff Lecture Series for Residents, University of Pittsburgh School of Medicine, Department of Medicine, Division of Hematology/Oncology, January 14, 2005; February 15, 2005; March 29, 2005; May 23, 2005; July 21, 2005.

Monoclonal Antibodies and The Paradigm Shift in the Treatment of B-Cell Lymphomas and Leukemias, Hematology/Oncology Fellows Lecture Series, University of Pittsburgh School of Medicine/Department of Hematology/Oncology, June 17, 2005.

Recent Advances in the Biology and Treatment of Low Grade Lymphomas, Lecture Series for Hematology/Oncology Fellows, University of Pittsburgh School of Medicine, Department of Medicine, Division of Hematology/Oncology; May 5, 2006.

Leukemia and Lymphoma, Houseteaching Staff Lecture Series for Residents, University of Pittsburgh School of Medicine/Department of Hematology/Oncology, March 2, 2006; May 1, 2006; June 8, 2006; July 18, 2006.

Recent Advances in the Biology and Treatment of Low Grade Lymphomas "Overview of Lymphoma" as part of Neoplasia Course; Facilitator for Case 4 "Erythocytosis" of PBL cases; January 2005.

"Recent Advances and Clinical Aspects in the Treatment of CLL," sponsored by Georgia Cancer Foundation, Atlanta, GA, March 23, 2006

Current Therapeutic Modalities in the Management of CLL, Cleveland, OH, April 20, 2006.

Mentored Jennifer Larson, 4<sup>th</sup> year Medical student, and assisted w/her poster presentation, summer 2005.

Mentored Christopher Marsh, MD, resident, and assisted him w/his presentation, spring 2006.

"Recent Advances and Clinical Aspects in the Treatment of CLL/SLL," Hematology/Oncology Fellows CME Lecture, University of Pittsburgh School of Medicine/Department of Hematology/Oncology, Sponsored by Berlex Pharmaceuticals, Soba Restaurant, Shadyside, Pittsburgh, PA, September 12, 2006.

"Recent Advances and Clinical Aspects in the Treatment of CLL/SLL," Oncology Grand Rounds, USC Keck School of Medicine, Los Angeles, California, sponsored by CBCE Speakers Corp., September 22, 2006.

"Clinical Care of Lymphoproliferative Disorders," Pittsburgh School of Medicine, Pittsburgh, Pennsylvania, part of Hematology Course for 4<sup>th</sup> year Medical School Students, January 11, 2007.

## **RESEARCH:**

### **1. Current Grant Support:**

<b>Grant Number (Funded)</b>	<b>Grant Title</b>	<b>Role in Project &amp; Effort (in cal. Mths.)</b>		<b>Years Inclusive</b>	<b>Source \$ Amount</b>
NIH RO1 CA72018	Ganglioside GD2 as Target for Immunotherapy in Melanoma	PI	3.0	8/01/05- 8/30/09	\$1,250,000 (direct)

C-Change	A Statewide Cancer Clinical Trials Network in Pennsylvania	PI	1.8	7/1/05-12/31/07	\$200,000 (direct)
Genentech	Fludarabine, cyclo-phosphamide and rituximab for untreated patients with chronic lymphocytic leukemia	PI	9.0	9/1/04 – 9/30/06	\$103,750 (direct)

## 2. Prior Grant Support

Louis Sklarow Memorial Fund, "Monoclonal Antibodies for B-Cell Lymphomas," Kenneth A. Foon, M.D., Principal Investigator, 7/1/86 - 6/31/87, \$42,000 (total cost).

NIH 1 RO1 CA43212-01, "Mechanisms of Interferon Action in Hairy-Cell Leukemia," Kenneth A. Foon, M.D., Principal Investigator, 9/30/86 - 6/30/89, \$173,960 (total direct cost).

NIH PO1 CA42768, "Radiopharmaceutical Diagnosis and Treatment of Cancer," Subproject: "Preclinical and Clinical Treatment with Monoclonal Antibodies to B-Cell Lymphomas," Kenneth A. Foon, M.D., Principal Investigator, 9/30/87 - 2/28/89, \$265,803 (total direct cost).

"A Phase I/II Study of High-Dose, Continuous-Infusion Recombinant Human Interleukin-2 with Non-Small Cell Lung Cancer and Resistant Lymphoma," Kenneth A. Foon, M.D., Principal Investigator, Hoffmann La Roche, Inc., 10/1/88 - 9/30/89, \$50,000 (total cost).

"A Phase I/II Clinical Investigation to Evaluate the Safety and Efficacy of Continuous Infusions of Recombinant Interleukin-2 and Phenylalanine Methyl Ester Pretreated Cells in Patients with Unresectable and/or Metastatic Melanoma and Renal Cell Cancer," Kenneth A. Foon, M.D., Principal Investigator, Dupont Corporation, 1/1/89 - 12/31/90, \$270,000 (total cost).

NIH RO1 CA47860, "Idiotype Approach to Therapy of Human T-Cell Leukemia," Malaya Chatterjee, Ph.D., Principal Investigator, Kenneth A. Foon, M.D., Co-Investigator (10%), 4/1/89 - 3/31/92, \$381,495 (total direct cost).

"Therapy of Renal Cell Carcinoma and Malignant Melanoma with Interleukin-2," Kenneth A. Foon, M.D., Principal Investigator (5%), Hoffmann La Roche, Inc., 6/1/90 - 5/31/91, \$39,000 (total cost).

NIH 1PO1 CA4767-03 (Consortium), "Monoclonal Antibody Therapy of Breast Cancer," R. Ceriani, M.D., Program Director; "<sup>111</sup>Indium-Labeled Monoclonal Antibody Imaging of

Metastatic Breast Cancer," Kenneth A. Foon, M.D., Principal Investigator (5%), 1/2/91 - 8/31/91, \$96,025 (total direct cost).

Buffalo Foundation Grant 857-0484A, "Feasibility Study of Anti-Idiotype Monoclonal Antibody Therapy for Patients with Cutaneous T-Cell Lymphoma," Kenneth A. Foon, M.D., Principal Investigator (5%), 3/1/91 - 2/29/92, \$7,000 (total cost).

NIH 1PO1 CA58880-01A2 (Program Project Grant), "Monoclonal Antibody Therapy for GI Cancer," Kenneth A. Foon, M.D., Principal Investigator (20%), 9/1/91 - 8/31/94, \$900,000 (total direct cost).

NIH RO1 CA54321-01 (Consortium), "Structure-Function of Tumor-Anti-Idiotype Antibodies," Heinz Köhler, M.D., Ph.D., Principal Investigator; "Generation of Tumor-Anti-Idiotypic Antibodies," Malaya Chatterjee, Ph.D., Principal Investigator, Kenneth A. Foon, M.D., Co-Investigator (10%), 7/1/91 - 6/30/94, \$130,902 (total direct cost).

Share Foundation, "Phase Ib Study of Monoclonal Anti-Idiotype Antibody Therapy for Patients with Metastatic Melanoma," 1/1/93 - 12/31/95, \$125,000 (total cost).

Ortho Pharmaceutical Corp. - Treatment of previously untreated chronic lymphocytic leukemia, 1994-95, \$50,000.

Tobacco & Health, Anti-Idiotype Vaccine for Human Small Cell Lung Carcinoma, 7/1/94-6/30/95, \$79,900 (total direct cost).

NCI 1PO1 CA57165-04 (Program Project Grant), "Monoclonal Antibody Therapy of GI Cancer", Kenneth A. Foon, M.D., Principal Investigator. Project 1. "Generation of Anti-Idiotype Tumor Vaccines", M. Chatterjee, Ph.D., Principal Investigator. 9/30/91 - 8/31/95, \$768,027 (direct cost), \$126,221 (indirect cost).

Berlex, Treatment of previously untreated low grade follicular lymphoma, Kenneth A. Foon, M.D., Principal Investigator, 1994-95, \$51,000.

NCI 5U10 CA46136-07, Southwest Oncology Group Clinical Study, Kenneth A. Foon, M.D., Principal Investigator, 1/1/88 - 12/31/97, \$507,164 (direct cost), \$244,266 (indirect cost).

NIH R01 CA60000-02, Anti-Idiotype Vaccine for Breast Cancer, Kenneth A. Foon, M.D., Principal Investigator, 12/1/94 - 11/30/97, \$477,406 (total direct cost), \$233,929 (indirect cost).

P20-, Planning Grants for Prospective Cancer Centers, Kenneth A. Foon, M.D., Principal Investigator, 8/1/95 - 7/30/97, \$350,000 (direct cost), \$171,500 (indirect cost).

NIH NCI R01 CA72773-03, "Immunotherapy of Cancer with Anti-Id Based DNA Vaccines", Principal Investigator, Sunil K. Chatterjee, Ph.D., 10/01/99- 12/31/99.

Lucille P. Markey Charitable Trust, Research Program Grant, Kenneth A. Foon, M.D., Principal Investigator, 1/2/95 - 2/15/99, \$1,900,000 (total direct cost).

NIH R03 CA79401-01, Anti-Idiotype Vaccine with IL-2 for Advanced Melanoma, Kenneth A. Foon, M.D., Principal Investigator, 11/1/98 - 10/30/00, \$145,646 (total direct and indirect cost).

Amgen, High Grade Lymphoma, Kenneth A. Foon, M.D., Principal Investigator, 2/1/95 - 2/1/99, \$15,000 (\$11,910 direct costs, \$3,090 indirect cost).

NIH R01 CA72018-01, Ganglioside GD2 as Target for Immunotherapy in Melanoma, Kenneth A. Foon, M.D., Co-Investigator, 8/1/96 - 6/30/01, \$1,142,854 (direct cost), \$1,679,995 (total cost).

Titan Pharmaceutical, Inc., Anti-Idiotype Antibody Vaccines, Kenneth A. Foon, M.D., Co-Principal Investigator, 7/1/96 - 6/30/01, \$1,750,000 (total direct cost).

NCI R03 CA72468-01, Comparison of Alum and QS-21 Based Anti-Idiotype Vaccines, Kenneth A. Foon, M.D., Principal Investigator, 12/1/96 - 11/30/98, \$147,000 (direct and indirect cost).

NCI U01 CA65748-01, New Therapeutic Approaches to Breast Cancer, Kenneth A. Foon, M.D., Principal Investigator, 12/1/94 - 11/30/98, \$842,019 (direct cost), \$412,589 (indirect cost).

NIH NCI U01CA65748, "New Therapeutic Approaches to Breast Cancer", Principal Investigator, Kenneth A. Foon, M.D., 1/1/95 - 12/31/99.

NIH NCI R03 CA68629, "Comparison of Alum and QS-21 Based Anti-Id Vaccione", Principal Investigator Kenneth A. Foon, M.D., 11/01/96 - 10/31/99

NIH RO1 CA80968-01, "Anti-Idiotype Antibody Vaccine Therapy of Human Colorectal Cancer," Consultant, Kenneth A. Foon, MD, 9/1/99 - 7/31/03.

## **2. Seminars and invited lectureships related to your research. (Five years)**

Anti-Idiotype Cancer Vaccines, The Children's Hospital Research Foundation Immunotherapy Conference, Cincinnati, OH, January 31, 2000.

Anti-Idiotype Antibodies Directed Against Gangliosides. Melanoma at the Millennium Conference, Phoenix, AZ, February 17, 2000

Anti-idiotype Vaccine that Mimics CEA: Novel therapeutic approach to colon cancer treatment. Case Western University, Ireland Cancer Center, Blood Club Seminar, Cleveland, OH, February 25, 2000.

Clinical and Immune Responses in Resected Colon Cancer patients Treated with Anti-Idiotype Monoclonal Antibody Vaccine that mimics the CarcinoembryonicAntigen. International Conference on Advances in Cancer Immunotherapy, Princeton, NJ, March 2 - 4, 2000.

Clinical and immune responses in resected colon cancer patients treated with anti-idiotype monoclonal antibody vaccine that mimics the carcinoembryonic antigen. 2<sup>nd</sup> Annual Walker's Cay Colloquium, Albert B. Sabin Vaccine Institute, Abaco, Bahamas, March 8 – 12, 2000.

The Barrett Cancer Center in the New Millennium. UC Board of Trustees, University of Cincinnati, Cincinnati, OH March 29, 2000.

Clinical Trials of Immunotherapeutics and Immunologic Monitoring. American Association for Cancer Research, April 3 – 4, 2000.

Targeted Therapies in the Treatment of Lymphoma, University of Louisville, Louisville, KY, Anti-idiotype Vaccine that Mimics the Carcinoembryonic Antigen. Dept. of Pathology and Laboratory Medicine, University of Cincinnati, Cincinnati, OH April 20, 2000.

Cancer Vaccines. Sabin 40<sup>th</sup> Annual Anniversary Celebration, University of Cincinnati, Cincinnati, OH April 28, 2000.

The Barrett Cancer Center and the New Millennium. UC Medical Center Orientation, Cincinnati, OH May 4, 2000.

Non-Hodgkin's Lymphoma. Miami Valley Hospital Tumor Board, Dayton, OH May 5, 2000.

Colorectal Cancer: Molecular Genetics and Therapeutic Advances. University-Wide Clinical Pathology Conference, Cincinnati, OH May 10, 2000.

Cancer Vaccines. 2000 American Society of Clinical Oncology, New Orleans, LA. May 19 – 22, 2000

Vaccine Therapies of Malignant Melanoma. Hematology-Oncology Grand Rounds, University of Cincinnati, Cincinnati, OH. May 26, 2000.

Welcome and Introduction, Cancer Survivor's Day, University of Cincinnati, Cincinnati, OH, June 4, 2000.

Vaccine Approaches to the Adjuvant Treatment of Colorectal Cancer. The Barrett Cancer Center and University of Cincinnati Annual Cancer Conference. Cincinnati, OH June 17, 2000.

Chronic Lymphoid Leukemias. Hematology-Oncology Grand Rounds Conference, University of Cincinnati, Cincinnati, OH. September 29, 2000.

Overview of Immune Flow Cytometry of Leukemias and Lymphomas. The Barrett Cancer Center, University of Cincinnati College of Medicine, Cincinnati, OH. October 7, 2000.

An Update on Cancer Vaccines. 12<sup>th</sup> Annual Western North Carolina Cancer Conference, Asheville, North Carolina, October 27, 2000.

Rubitecan: An Effective New Therapy in Pancreatic Cancer. Chemotherapy Foundation Symposium XVIII, New York City, New York, November 8, 2000.

Vaccine in the Treatment of GI Malignancies. Gastrointestinal Cancer Research Conference 2000, Orlando, Florida, November 16 – 18, 2000.

Anti-Idiotype Antibody that Mimics Carcinoembryonic Antigen: Novel new Approach to Colon Cancer Immunotherapy. The Molecular Medicine of Colorectal Cancer, Keystone Symposia on Molecular and Cellular Biology, Taos, New Mexico, February 1 – 2, 2001.

Expanding Options in the Treatment of Non-Hodgkin's Lymphoma". Medical City Tumor Conference, Medical City Dallas Hospital, Dallas, TX. March 21, 2001.

Monoclonal Antibodies in Combination with Chemotherapy for the Treatment of Non-Hodgkin's Lymphoma. IDEC Pharmaceuticals Corporation, Dallas, TX. March 21, 2001.

Clinical Results: A Fully Human Anti-EGFr Antibody In Patients With Advanced Cancer: Molecular Targets and Cancer Therapeutics, AACR-NCI-EORTC International Conference. October 29 – November 2, 2001

Effects of ABX-EGF, A Fully Human Anti-EGFr Antibody, in Patients with Advanced Cancer. Cancer Research Institute Antibodies 2002 Symposium: New York, NY, March 19 – 20, 2002

Current Status of Vaccine Therapy in Malignancies. Moving Beyond The Ordinary; Fourth Annual Palm Beach Cancer Symposium, Delray Beach, FL., March 22-23, 2002.

ABX-EGF, A Fully Human Anti-Epidermal Growth Factor Receptor (EGFr) Monoclonal Antibody (MAb) In Patients With Advanced Cancer. Phase I Clinical Trials: American Society of Clinical Oncology: Gaylord Palms Resort and Convention Center, Kissimmee, FL. May 19 – 21, 2002.

ABX-EGF, A Fully Human Anti-Epidermal Growth Factor Receptor (EGFr) Monoclonal Antibody (MAb) for the Treatment of Patients with a Variety of EGFr Positive Malignancies. Anti-Cancer Drug Discovery & Development Summit 2002: Princeton, NJ, June 17 – 19, 2002.

ABX-EGF, A Fully Human Anti-EGFR Monoclonal Antibody For The Treatment Of Advanced Cancer. First International Congress on Targeted Therapies: Washington, DC, August 16-18, 2002.

Monoclonal Antibodies/Other Immune Directed Strategies In Cancer Management. Emerging Therapeutics in Cancer: Update on Prostate Cancer, 7<sup>th</sup> Annual National VA Oncology Symposium, Alexandria, VA, October 2 – 4, 2002.

Nipent® (pentostatin) Experience in the Treatment of CLL. 2005 ASCO Annual Meeting, May 13-17, 2005.

International Vaccine Conference Anti-Idiotype Vaccines Mimicking the CEA and GD-2 Gangliosides, Italy, 2004.

Grand Rounds, University of Pittsburgh School of Pharmacy, Anti-Idiotype Vaccines Mimicking the CEA and GD-2 Gangliosides, Italy, 2004.

ECOG 2005 Fall Meeting, Anti-Idiotype Antibody That Mimics the GD2 Ganglioside, Tampa, FL, Nov. 20, 2005.

Reason for Hope – Advances in the Treatment of CLL – “Reason to Hope” Series. UPMC St. Cancer Center – St. Clair, Upper St. Clair, PA, Nov. 30, 2005

### **3. Other Research Related Activities**

#### **Patents**

##### **Tri-Gem (1A7)**

Patent Number: 5,612,030  
Date of Patent: 3/18/97

“Anti-idiotype monoclonal antibody 1A7 and use for the treatment of melanoma and small cell carcinoma”

##### **TriAb (11D10)**

Pending Serial Number: 08/766,350  
Date Filed: 12/13/96  
“Murine monoclonal anti-idiotype antibody 11D10 and methods of use thereof”

##### **CeaVac (3H1)**

Pending Serial Number: 08/579940  
Date Filed: 12/28/95 (whole antibody)  
“Murine monoclonal anti-idiotypic antibody 3H1”

Pending Serial Number: 08/579916  
Date Filed: 12/28/95

Member, TVC Advisory Board 2006-present

Member, Spectrum Advisory Board 2006-present

Faculty, Berlex Speakers Bureau 2006-present

Faculty, Genentech Speakers Bureau 2006-present

Faculty, CBCE Speakers Bureau 2003-present

Esai Pharmaceutical Advisory Board	2003-present
Scientific Advisor, Automated Cell	2003-present
Supergen Scientific Advisory Board	2003-present
Editorial Board, Journal of Clinical Immunology	1993-present
Member, Scientific Advisory Board, National Surgical Adjuvant Breast and Bowel Project	1996-present
Editorial Board, Cancer Biotherapy & Radiopharmaceuticals	2005-present
Editor, Journal of Experimental Biology and Medicine, Translational Research Section	2005-present
Co-Editor, Expert Opinion on Biological Therapy, Future Perspectives Section	2006-present
Associate Editor, Clinical Cancer Research	1998-present
Editorial Board, Journal of Immunotherapy	1982-1996
Clinical Sciences Study Section (Subcommittee 4) Division of Research Grants	1986-1990
Associate Editor, Cancer Research	1987-2003
Associate Editor, Antibodies, Immunoconjugates and Radiopharmaceuticals	1987-1990
Editorial Board, Contemporary Oncology	1990-1994
Grants Review Committee for the American Cancer Society	1993-1996
Board of Directors, The Society for Biological Therapy	1995-1997
Editorial Board, Journal of Biotherapy	1995-2000
Board of Advisors, NeoRx Corporation,	1985-1988

Seattle, WA

P01, Member, Memorial Sloan Kettering Cancer Center, NCI Site Visit committee, New York, NY	May 1, 1985
P01, Member, NCI Special Review Committee	October 1, 1985
P01, Member, Stanford Medical Center, NCI Site Visit Committee, Stanford, CA	October 1, 1985
National Research Service Award Advisory Committee, National Institute of Health	1985-1989
P01, University of California at Davis, Sacramento, CA, Member, NCI Site Visit Committee	March 1, 1988
P01, Member, Immunomedics, Site Visit Committee, Morris Plains, NJ	December 5, 1990
P01, Stanford Medical Center, Member, NCI Site Visit Committee, Stanford, CA	November 11, 1991
P30, Member, University of Nebraska Cancer Center, NCI Site Visit Committee, Omaha, NE	February 10, 1992
P50, Member, NCI Special Study Section for AIDS Center Grants	July 13, 1993
Board of Advisors, Inex Pharmaceuticals Corp. Vancouver, B.C.	1994-1995
Health & Environment Laboratories, Eastman Kodak Company, Rochester, NY	1994-1996
P01, University of California at Davis, Sacramento, CA, NCI Site Visit Committee Chairman	April 13, 1994
2P01CA59326-03, Gene Therapy for Cancer, University of California at Los Angeles, Member, NCI Site Visit Committee	June 19, 1994
Scientific Review Panel, Israel Cancer Research	1995-2001

Fund, New York, NY

2P01CA4499108, Theray of Lymphoma/Leukemia February 14, 1995  
with Monoclonal Antibodies, Fred Hutchinson  
Cancer Research Center, Member, NCI Site Visit  
Committee

1P30CA6953301, Oregon Cancer Center, June 12, 1995  
Member, NCI Site Visit Committee

1P30CA6953301, Oregon Cancer Center, Member August 3, 1995  
NCI Site Visit Committee

NSABP Scientific Advisory Board, Operations February 6, 1996  
Center Site Visit, Pittsburgh, PA

2P01CA5935005, Memorial-Sloan Kettering July 7, 1996  
Cancer Center, Gene Therapy Program, NCI  
Site Visit Committee Chairman

1P30CA6953301A1 Oregon Cancer Center, October 7, 1996  
Member, NCI Site Visit Committee

Director, Scientific Advisory Board, Titan 1996-2001  
Pharmaceuticals, Inc., South San Francisco, CA

NCI Scientific Review Group-Subcommittee H 1997-2001

NCI Clinical Oncology Study Section 1999-2001

ACOSOG Site Visit, Chicago, IL Sept. 21, 1999

SuperGen Advisory Board Meeting, Phoenix, AZ January 15, 2000

SuperGen Advisory Board Meeting, Phoenix, AZ January 13-16, 2000

NCI GI Intergroup State-of-Science Symposium February 15, 2000

NCI Clinical Oncology Study Section, March 20, 2000  
Bethesda, MD

IDEC Pharmaceuticals Meeting, San Diego May 7-8, 2000  
CA

American College of Surgeons/Tritan May 16, 2000  
Pharmaceutical Meeting, Chicago, IL

NCI NIH Scientific Review Group-Subcommittee H Site Review, Rochester, MN	June 7-9, 2000
SuperGen, Rubitecan Advisory Board Meeting Maui, HI	June 13-17, 2000
American College of Surgeons Semiannual Meeting, Chicago, IL	June 24, 2000
NCI Clinical Oncology Study Section, Bethesda, MD	July 7-14, 2000
Abbott Pharmaceutical Advisory Panel, Chicago, IL	Dec. 8-9-, 2000
Fulcrum Renal Cell Advisory Board Mtg. New York	Jan. 14-15, 2001
NCI Breast Intergroup Retreat, Washington, DC	Jan. 18-19, 2001
NCI Scientific Review Group-Subcommittee H Teleconference	March 15, 2001
PO1, Member, NCI Scientific Review Group	November 2005
ICRF Scientific Review Group	March 2006

#### **LIST OF CURRENT RESEARCH INTERESTS:**

Current grant funded research is a phase III clinical trial using the TriGem anti-idiotype vaccine for melanoma developed in our laboratories. At the UPCI, I am developing new protocols for a variety of hematologic malignancies including Hodgkin's disease, lymphomas, chronic lymphocytic leukemia, multiple myeloma, chronic myelogenous leukemia, acute myelogenous leukemia, and myelodysplastic syndromes. A collaboration with the NCI and Therion Biopharm for a vaccine therapy of CLL has been established. New collaborations with UPCI investigators are ongoing to generate dendritic cell vaccines for B-cell lymphoma and multiple myeloma. We have established a chronic lymphoid malignancies/multiple myeloma clinical center that will allow us to expand these translational research programs. In the area of solid tumors, we are establishing new areas of translational research with UPCI investigators generating a variety of dendritic cell vaccine approaches, and with investigators at the National Cancer Institute and Biotechnology companies using viral vectors for gene therapy.

**SERVICE:****1. University and Medical School**

1989 - 1990	Search Committee for Chairman, Department of Radiation Oncology, Roswell Park Cancer Institute
1989 - 1990	Search Committee for Chairman, Department of Cytogenetics, Roswell Park Cancer Institute
1999 - 2001	Oncology-Hematology Care Executive Committee, University of Cincinnati
1999 - 2001	Ohio Cancer Incidence Surveillance System Advisory Board
	Ohio Department of Health
1999 - 2001	Hematology-Oncology Fellow Evaluation Committee, University of Cincinnati
1989 - 1990	Search Committee for Chairman, Department of Pediatrics, Roswell
1990	Head, Search Committee for Infectious Disease Specialist, Roswell Park Cancer Institute
1990 - 1991	Search Committee for Chairman, Department of Microbiology, SUNY
1989 - 1990	Radiation Safety Committee, Roswell Park Cancer Institute
1989 - 1990	Quality Assurance Committee, Roswell Park Cancer Institute
1989 - 1991	American Society of Hematology, Neoplastic Committee
1990	Head, Search Committee for Pulmonologist/Intensivist, Roswell Park
1991	Head, Search Committee for Cardiologist, Roswell Park Cancer Institute Cancer Institute
1990 - 1991	Vice President, Medical Staff, Roswell Park Cancer Institute
1993	Head, Search Committee for Chairman of Radiation Medicine,
1989 - 1991	American Society of Clinical Oncology, Program Committee
1991 - 1992	American Association for Cancer Research, Program Committee
1992 - 1994	Clinical Immunology Society, Program Committee
1992 - 1989	Internal Medicine Chairman's Advisory Committee
1994 - 1999	Liaison Committee on Medical Education, University of Kentucky
1994 - 1996	Medical Center Clinical Sciences Area Advisory Committee, University of Kentucky
1996 - 1999	General Clinical Research Center Advisory Committee, University of Kentucky
1999 - 2001	Chair, Cancer Steering Committee, University Hospital, University of Cincinnati
1999 - 2001	Vontz Steering Committee, University of Cincinnati
1999 - 2001	Chair, Internal Advisory Committee, Barrett Cancer Center, University of Cincinnati
1999 - 2001	Chair, Scientific Review Committee, Barrett Cancer Center, University of Cincinnati
2003-Present	Director of the University of Pittsburgh Cancer Institute, GCRC

2003-Present	Member of the University of Pittsburgh Medical Center GCRC Advisory Board
2005-Present	Co-Chair, PAC3, Pennsylvania Cancer Control Consortium
2003-Present	Co-Leader, Biologic Therapeutics Program, University of Pittsburgh
2003-Present	Co-Leader, Hematologic Malignancy Program, University of Pittsburgh
2003-Present	Director of Clinical Investigations, University of Pittsburgh Cancer Institute

## **2. Community Activities**

1985-1987	Board of Trustees, Michigan Chapter, Leukemia Society of America
1994-1995	American Cancer Society, Board of Directors, Fayette County Unit
1994 - 1996	Health and Environment Laboratories, Eastman Kodak Company, Rochester, NY
1998	Department of Insurance, Commonwealth of Kentucky